

REMARKS

Claims 1-20, 22-28, and 30 are pending in the present application.

At the outset, Applicants wish to thank Examiner Soroush and Examiner Padmanabhan for the helpful and courteous discussion with their undersigned Representative on May 2, 2007. During this discussion, several amendments and arguments were discussed to address the outstanding rejections. The content of this discussion is believed to be reflected in the amendments and remarks herein. Reconsideration of the outstanding rejections is requested.

The rejections of Claims 22-29 under 35 U.S.C. §112, first paragraph (enablement), is obviated by amendment.

The Examiner alleges that the specification fails to enable the prevention of inflammatory disease by administering a composition as presently claimed. Applicants make no statement with respect to the propriety of this rejection, but to facilitate expedient examination, Claim 22 has been amended to replace the phrase “preventing an inflammatory disease” with “depressing the progression of rheumatoid arthritis”. Therefore, this ground of rejection is now moot.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejections of (a) Claims 14-17 and 20 under 35 U.S.C. §103(a) over Moretti and Meisner; and (b) Claims 18 and 19 under 35 U.S.C. §103(a) over Moretti and Meisner in view of Fisher et al and Ansel et al, are respectfully traversed.

This ground of rejection is based on the Examiner’s allegation that it would be

obvious to co-administer ornithine and valine to treat arthritis. This position is based on the asserted disclosure that Moretti teaches oral or parenteral administration of ornithine to treat inflammatory bowel disease, heptao-splenomegaly associated with inflammatory disease, rheumatoid arthritis, and connective disease. The Examiner alleges that it would be obvious to combine this disclosure with Meisner, who is asserted as teaching a composition to treat tissue degenerative inflammations and inflammatory diseases with valine.

Applicants continue to disagree with this rejection for the reasons set forth in the response filed November 27, 2006. However, in the interest of expedient examination, Applicants have amended Claim 14 to define the branched amino acid(s) for use in the claimed method as being “at least one branched amino acid is a branched amino acid or a mixture of two or more branched amino acids and said branched amino acid is selected from the group consisting of (a) leucine, (b) leucine and valine, (c) leucine and isoleucine, (d) isoleucine, (e) isoleucine and valine, and (f) isoleucine, leucine, and valine.” Thus, the specific co-administration of ornithine and valine, which the Examiner alleges is suggested by Moretti and Meisner is no longer claimed. There being no motivation and requisite expectation of success found in Moretti or Meisner for administration of compositions as presently claimed, the claimed invention would not be obvious in view of these combined disclosures.

Further, Applicants direct the Examiner’s attention to the present specification which clearly establishes the benefits flowing from the claimed invention none of which are apparent from the disclosures of Moretti or Meisner. In this regard, Applicants specifically wish to note that Moretti merely disclose that carnitine reduces the ceramide levels in a cell, without providing any data of the therapeutic effect. They also fail to give a sufficient explanation of the relationship between ceramide in a cell and rheumatism. There is also no

data demonstrating that a basic amino acid, other than carnitine (i.e., ornithine) has an effect of the same kind. With respect to the beneficial effects flowing from the co-administration of ornithine and at least one branched amino acid, the Examiner is reminded of Table 6 of Example 9 (below).

Table 6: Effect of Combined Ornithine and BCAA on CIA

Drug	Ratio of Individuals with Arthritis (%)	Arthritis Score
Control Group	100	3.2
Ornithine	30	0.8
BCAA	30	1.2
Combined Group	0	0

These results unequivocally show that the combined administration of ornithine and branched amino acids exemplified by L-isoleucine:L-leucine:L-valine at a ratio of 1:2:1.2 absolutely inhibited disease development, which could not be achieved with the individual administration of the active ingredients. Applicant submit that these results would not flow from the limited disclosure of Moretti and Meisner.

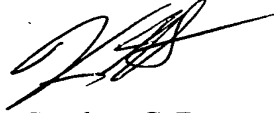
Fisher et al and Ansel et al are merely cited as disclosing food and drinks to which the active ingredients may be added. However, these references fail to compensate for the aforementioned deficiencies in the disclosures of Moretti and Meisner. As such, even when viewing the combined with the disclosures of Moretti and Meisner, the present invention would not be obvious.

Accordingly, Applicants request withdrawal of these grounds of rejection.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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